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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,483

02/07/2002

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ORT-1588

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03/05/2004

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/071,483

**Applicant(s)**

DAX ET AL.

**Examiner**

Tamthom N. Truong

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5,8,9,12 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 3-5,8,9 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/17/03
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment of 11-10-03 has been fully considered. The amendment has cancelled claims 1, 6, 7, 10, 11, and 13-16. Thus, only claims 2-5, 8, 9, 12, and 17-19 remain for consideration.

Although the amended claim 2 has overcome the previous rejections of 102(b) based on **Islam et. al.** (WO'682), and 102(e) based on **Dax et. al.** (US'025 & US'354), it introduces new matter since part of the proviso has no support in the instant disclosure. Also, the amended claim 2 has clarified the relationship of "p", "q", and provided antecedent basis for claim 12, therefore, the rejection of 112/2<sup>nd</sup> is also withdrawn herein along with the 102 rejections.

However, a review of the method and composition claims prompts the following new ground of rejection.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Lack of Written Description:** Claims 2, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The proviso in claim 2 does not have support in the instant disclosure entirely. That is, the original proviso does not exclude Z as a “heteroaryl” group. Also, the original proviso requires that when L is (N-methylene)-4-acetylpiperidin-4-yl, then Z is phenyl or naphthyl, and **Y is carbonyl**. The new proviso, however, does **not** restrict Y when L (N-methylene)-4-acetylpiperidin-4-yl, and Z is aryl or heteroaryl. It is not apparent which species of the invention are actually excluded since the new proviso is inconsistent with the one in the disclosure. Note, **even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.**

2. **Scope of Enablement:** Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the pharmaceutical composition and treatment of some disorders associated with NPY receptor subtype 5, does not reasonably provide enablement for the pharmaceutical composition and treatment of other disorders such as: **obesity, and bulimia nervosa**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 17 recites “a method of treating disorders and diseases associated with NPY receptor subtype 5...” which encompasses the treatment for diseases such as obesity and bulimia nervosa. It is not understood how one chemical agent can help losing weight in obesity, and yet, can treat bulimia nervosa. Such a contradicting treatment renders claim 17 not enabled for its entire scope.

Claims 18 and 19 recite “a pharmaceutical composition for the treatment” of a number of

diseases associated with NPY including **obesity** and **bulimia nervosa**. Again, it is rather impossible for one pharmaceutical composition to reduce weight in obesity, and yet, increase weight or appetite in bulimia nervosa. There has never been one drug that can treat two disorders with opposite symptoms. Therefore, claims 18 and 19 are not enabled for their entire scope.

#### ***Claim Objections***

3. Claims 3-5, 8, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior arts of record do not teach the species recited in the above claims.

#### ***References cited on PTO-892***

4. An update search yields references listed on PTO-892, which show state of the art only. While they teach tetrahydronaphthalenyl derivatives, they fail to teach the combination of -NH-Y-L-Z as in the formula claimed herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-T (~10 am ~ 8:30 pm) starting from February 22<sup>nd</sup>, 2004.

Application/Control Number: 10/071,483

Page 5

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

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March 2, 2004

  
RICHARD L. RAYMOND  
ACTING SPE  
ART UNIT 1624